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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,279	12/11/2001	Johnny Paul Speir	140-067a	2332
27776	7590	09/04/2008	EXAMINER	
WARD & OLIVO			LIN, JERRY	
SUITE 300				
382 SPRINGFIELD AVENUE			ART UNIT	PAPER NUMBER
SUMMIT, NJ 07901			1631	
			MAIL DATE	DELIVERY MODE
			09/04/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/014,279	SPEIR, JOHNNY PAUL	
	<b>Examiner</b>	<b>Art Unit</b>	
	JERRY LIN	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 27 May 2008.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 30-33 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 30-33 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____ .	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

1. Applicants' arguments and amendments, filed May 27, 2008, have been fully considered and they are deemed to be persuasive in-part. However, in light of the amendments, the following rejections are deemed necessary. The following rejections are newly applied as necessitated by amendment. They constitute the complete set presently being applied to the instant application.

### ***Status of the Claims***

Claims 30-33 are under examination.

### ***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have amended claim 30 to include the step of "dynamically calculating and then displaying the error...." However, it is unclear what is meant by "dynamically" with regard to "calculating." The specification does not use this term. A search of the prior art does not reveal any commonly accepted definition of this term. Thus, it unclear as to what the metes and bounds of recited limitation are. Claims 31-33 are also rejected for depending from this claim.

Claims 30 recites “each species” in line 13. However it is unclear to what these species are referring. The instant claim recites ions, the sample, or metabolic products which may be labeled as a species.

Response to arguments

3. Applicants have responded to this rejection by amending “each species” in line 8 to “each metabolic product.” However, it is still unclear to what “each species” in line 13 is referring. This rejection is maintained from the previous office action.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> Paragraph***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 30-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants have amended claim 30 to include the step of "dynamically calculating and then displaying the error...." However, the term “dynamically” does not appear in the specification or the claims as originally filed. Page 16 of the specification does contain an example of calculating an error, however there is no recitation that the

calculation is done dynamically. Because amended limitation does not appear in the specification or the claims as originally filed, the instant claims contain NEW MATTER.

6. Claims 30-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include:

(1) the quantity of experimentation necessary – neither the specification or the claims define the term "dynamically." Thus, one of skill in the art would have to perform undue experimentation to determine a dynamic calculation. See below for additional rationale.

(2) the amount of direction presented - Neither the specification or the claims define the term "dynamically."

(3) the presence or absence of working examples - The specification does show calculating errors on page 16, however, it does not show "dynamically calculating" errors.

(4) the nature of the invention - The invention is drawn to a method of determining molecular weight of a drug dose sample using a mass spectrometer.

(5) the state of the prior art - A search of the prior art does not reveal any commonly accepted definition of "dynamically calculating" errors.

(6) the relative skill of those in the art - The relative skill of those in the art is high.

(7) the predictability or unpredictability of the art – It is predictable to apply calculations to experimental data, however, one of skill must know what calculations to apply in order to perform the method.

(8) the breadth of the claims - The claims are drawn to a method where a drug-dosed sample is introduced to a mass spectrometer, the molecular weight of each metabolic product is determined, the error associated with the calculated molecular weight is determined, and identifying each species by comparing the empirical formula to a database of formulas.

Applicants have amended claim 30 to include the step of "dynamically calculating and then displaying the error...." However, it is unclear as to how one of skill in the art is to "dynamically" calculate an error. A search of the prior art does not reveal any commonly accepted definition of this term. Furthermore, the specification does not use this term. Page 16 of the specification does contain an example of calculating an error, however there is no recitation that the calculation is done dynamically. Although applying a calculation to experimental data is predictable, one of skill in the art must know what calculation to use. If one of skill in the art does not know what calculation to

use, one of skill in the art must perform undue experimentation to derive the correct calculations. Because neither the specification nor the prior art reveal how one of skill in the art is to dynamically calculate an error, one of skill in the art must perform undue experimentation to determine how to dynamically calculate an error.

***Withdrawn Rejections***

7. The rejection of claims 30-33 made under 35 U.S.C. §103 in the previous office action has been withdrawn, because it is unclear how one of skill in the art is to perform dynamically calculating an error. Given that one of skill in the art would not have known how to perform the claimed method for the reasons set forth above, one of ordinary skill in the art would not have found it obvious in the references of Dasseux et al., Ji et al., and Mighell et al. Applicant is advised, however, amending the instant claims to overcome the above rejections may result in reinstatement of the rejection made under 35 U.S.C. §103 in view of Dasseux et al., Ji et al., and Mighell et al.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY LIN whose telephone number is (571)272-2561. The examiner can normally be reached on 7:00-5:30pm, M-TH.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. L./  
Examiner, Art Unit 1631

/Marjorie Moran/  
Supervisory Patent Examiner, Art Unit 1631